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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/308,192      07/14/99      BAXTER

A      229752000600

EXAMINER

HM12/0917

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WASHINGTON DC 20006-1888

DEVLIS

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

09/17/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.  
**09/308,192**

Applicant(s)

**Baxter**

Examiner

**S. Devi, Ph.D.**

Art Unit

**1645**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Jun 14, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 22 ~~is/are~~ pending in the application.
- 4a) Of the above, claim(s) 5, 6, 11-19 and 22 ~~is/are~~ withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-10 ~~is/are~~ rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

Application SN 09/308,192  
Art Unit: 1645

## **DETAILED ACTION**

### **Applicant's Amendment**

- 1) Acknowledgment is made of Applicant's amendment filed 06/14/01 (paper no. 11) in response to the Office Action mailed 12/14/00 (paper no. 8). With this, Applicant has amended the specification.

### **Status of Claims**

- 2) Claims 20 and 21 have been canceled via the amendment filed 06/14/01.  
Claims 1-4 and 7-10 have been amended via the amendment filed 06/14/01.  
Claims 1-19 and 22 are pending.  
Claims 1-4 and 7-10 are under examination.

### **Rejection(s) Moot**

- 3) The rejection of claims 20 and 21 made in paragraph 2 of the Office Action mailed 12/14/00 (paper no. 8) under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicant's cancellation of the claims.
- 4) The rejection of claims 20 and 21 made in paragraph 3 of the Office Action mailed 12/14/00 (paper no. 8) under 35 U.S.C § 112, second paragraph, as being indefinite, and under 35 U.S.C § 101, is moot in light of Applicant's cancellation of the claims.

### **Rejection(s) Withdrawn**

- 5) The rejection of claims 1-4 and 7-10 made in paragraph 2 of the Office Action mailed 12/14/00 (paper no. 8) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendments to the claims or the base claim(s).
- 6) The rejection of claim 10 made in paragraph 5 of the Office Action mailed 12/14/00 (paper no. 8) under 35 U.S.C § 112, first paragraph, as being non-enabled, is withdrawn.
- 7) The rejection of claims 1-3 and 7-10 made in paragraph 8 of the Office Action mailed 12/14/00 (paper no. 8) under 35 U.S.C § 102(b) as being anticipated by Robinson *et al.* (*J. Clin. Lab. Immunol.* 24: 171-176, 1987) is withdrawn.

### **Rejection(s) Maintained**

8) The rejection of claims 1-4 and 7-9 made in paragraph 7 of the Office Action mailed 12/14/00 (paper no. 8) under 35 U.S.C § 102(b) as being anticipated by Qin *et al.* (*J. Immunol.* 150: 2072-2080, 1993, already of record) is maintained for reasons set forth therein and here below.

Applicant contends that Qin's CFA contains "whole killed" *M. tuberculosis* and that BCG is an attenuated strain of "whole and live" *M. bovis* [Emphasis in original]. Applicant states that he/she is claiming only the use of effective cell wall components of *Mycobacterium* and immunomodulatory therapy using the same. Applicant further states that Qin found that MDP did not prevent the onset of diabetes.

Applicant's arguments have been carefully considered, but are not persuasive. Applicant is claiming a method that involves administering one or more components of the cell wall of *Mycobacterium*, which include both isolated and non-isolated cell wall components. Qin *et al.* teach a method of treating or preventing the development of type I diabetes (i.e., IDDM) in non-obese diabetic mice (i.e., mammals) comprising administering an emulsion of CFA or complete Freund's adjuvant, or a BCG vaccine. CFA contains the adjuvanting cell wall of *Mycobacterium* strain, H37Ra (i.e., *M. tuberculosis*) (see abstract; the paragraph bridging pages 2072 and 2073, and the second paragraph under 'Materials and Methods'). The antigenic component is contained in saline, i.e., a pharmaceutically acceptable carrier or diluent and administered in MDP (see second paragraph under 'Materials and Methods'). Qin *et al.* also teach that CFA treatment prevents the adverse effects, or the autoimmune destruction of transplanted syngeneic islets in diabetic NOD mice (see page 2073, left column, lines 4-6). That Qin's BCG vaccine and the CFA necessarily comprise one or more cell wall components that comprise mycolyl-arabinogalactan-peptidoglycan or a component thereof, is inherent from the teachings of Qin *et al.* since it is well known in the art that mycobacteria or mycobacterial cell wall contain such a component. The Applicant's remark that Qin's MDP did not prevent the onset of diabetes is not relevant, because instant claims are not drawn to a method of treating diabetes by administering a mammal with an MDP, but with one or more mycobacterial cell wall components. The rejection stands.

**Rejection(s) under 35 U.S.C. § 103**

9) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

10) Claims 1 and 10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Qin *et al.* (*J. Immunol.* 150: 2072-2080, 1993, already of record).

The teachings of Qin *et al.* are explained above, which do not expressly teach the use of the claimed method in a human. However, Qin *et al.* teach that NOD mice share genetic and pathologic features with human type I diabetes (see page 2072, left column). As indicated in the last sentence of the 'Discussion', one of the purposes of Qin *et al.* was to understand the prevention of autoimmune diabetes by immunotherapy.

Given the knowledge that NOD mice spontaneously develop IDDM which has many immunological and pathological similarities to human IDDM, it would have been obvious to one of ordinary skill in the art at the time the invention was made to extrapolate Qin's method of immunotherapy in non-human mammals, such as, mice to humans to produce the method of the instant invention, with a reasonable expectation of success. A skilled artisan would be motivated to produce the instant invention for the expected benefit of providing a method of immunotherapy for IDDM in humans.

Application SN 09/308,192  
Art Unit: 1645

Claims 1 and 10 are *prima facie* are obvious over the prior art of record.

**Remarks**

- 11) Claims 1-4 and 7-10 stand rejected.
- 12) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242.
- 13) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.45 a.m to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 2001

*SD*  
S. DEVI, PH.D.  
PRIMARY EXAMINER